

Each immunization training program shall be accredited by the Accreditation Council for Pharmacy Education.

Section 4. Section 20-633-4(a) of the Regulations of Connecticut State Agencies is amended to read as follows:

(a) The course of study for the immunization training program shall include current guidelines and recommendations of the Department of Health and Human Services Centers for Disease Control and Prevention for vaccination of adult patients accredited by the Accreditation Council for Pharmacy Education.

**Statement of purpose:** The purpose of these regulations is to conform existing regulations to the changes made by Public Act 10-82 to Conn. Gen. Stat. Section 20-633.

Be it known that the foregoing regulations are amended as hereinabove stated by the aforesaid agency pursuant to Secs. 4-168 and 20-663 of the General Statutes, as amended by Public Act No. 82 of the 2010 Public Acts, after publication in the Connecticut Law Journal on December 6, 2011, of the notice of the proposal to amend such regulations, and the holding of an advertised public hearing on the 10<sup>th</sup> day of January, 2012.

Wherefore, the foregoing regulations are hereby amended as hereinabove stated, effective when filed with the Secretary of the State.

In Witness Whereof: March 7, 2012, William M. Rubenstein, Commissioner.

Approved by the Attorney General as to legal sufficiency in accordance with Sec. 4-169, as amended, Connecticut General Statutes: March 23, 2012.

Approved by the Legislative Regulation Review Committee in accordance with Sec. 4-170, as amended, of the General Statutes: July 24, 2012.

Two certified copies received and filed, and one such copy forwarded to the Commission on Official Legal Publications in accordance with Sec. 4-172, as amended, of the General Statutes, Secretary of the State: July 30, 2012.

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## DEPARTMENT OF CONSUMER PROTECTION

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### Non-Sterile Compounding

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The Regulations of Connecticut State Agencies are amended by adding sections 20-576-69 to 20-576-73, inclusive, as follows:

#### Sec. 20-576-69. Definitions

As used in sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies:

- (1) "Commission" means the Commission of Pharmacy;
- (2) "Non-sterile compounding pharmacy" means a pharmacy licensed pursuant to section 20-594 of the General Statutes that dispenses non-sterile compounded pharmaceutical products, but does not include a pharmacy that is part of a licensed hospital; and
- (3) "Non-sterile compounded pharmaceutical product" means a drug dosage form, a dietary supplement or a finished device made from the preparation of one or more substances.

#### Sec. 20-576-70. Purpose

The purpose of sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies is to ensure positive patient outcomes through the provision of standards for (1) pharmacist care; (2) the preparation, labeling, and distribution of non-sterile compounded pharmaceutical products by pharmacies

licensed pursuant to section 20-594 of the General Statutes; and (3) product quality and characteristics.

#### **Sec. 20-576-71. Standards**

(a) Sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies shall apply to all non-sterile compounded pharmaceutical products, notwithstanding the location of the patient, including, for example: Home, hospital, nursing home, hospice, or doctor's office.

(b) A non-sterile compounding pharmacy shall comply with sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies, and the current United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations. The United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations may be obtained at [http://www.pharmacopeia.cn/v29240/usp29nf24s0\\_c795.html](http://www.pharmacopeia.cn/v29240/usp29nf24s0_c795.html).

(c) A non-sterile compounding pharmacy may provide non-patient specific non-sterile compounded pharmaceutical products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision, except that the quantity shall be limited to a thirty day supply.

#### **Sec. 20-576-72. Policy and procedure manual**

A non-sterile compounding pharmacy shall prepare and maintain a policy and procedure manual for the compounding, dispensing, delivery, administration, storage, and use of non-sterile compounded pharmaceutical products. The policy and procedure manual shall be in compliance with the United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations.

#### **Sec. 20-576-73. Hours**

A non-sterile compounding pharmacy shall be open at least thirty-five hours per week unless granted a waiver by the commission pursuant to section 20-576-59 of the Regulations of Connecticut State Agencies.

**Statement of purpose:** Connecticut General Statutes, Section 20-576(a)(2) permits the Commissioner of Consumer Protection, with the advice and assistance of the Commission of Pharmacy, to adopt regulations specifying classes of pharmacies and setting requirements for specific classes of pharmacies. These regulations establish requirements for pharmacies classified as non-sterile compounding pharmacies.

Be it known that the foregoing regulations are adopted by the aforesaid agency pursuant to Secs. 4-168 and 20-576(a) of the General Statutes, after publication in the Connecticut Law Journal on April 24, 2012, of the notice of the proposal to adopt such regulations, and the holding of an advertised public hearing on the 30<sup>th</sup> day of May, 2012.

Wherefore, the foregoing regulations are hereby adopted, effective when filed with the Secretary of the State.

In Witness Whereof: July 17, 2012, William M. Rubenstein, Commissioner.

Approved by the Attorney General as to legal sufficiency in accordance with Sec. 4-169, as amended, Connecticut General Statutes: August 13, 2012.

Approved by the Legislative Regulation Review Committee in accordance with Sec. 4-170, as amended, of the General Statutes: October 23, 2012.

Two certified copies received and filed, and one such copy forwarded to the Commission on Official Legal Publications in accordance with Sec. 4-172, as amended, of the General Statutes, Secretary of the State: November 2, 2012.

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